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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,844	08/06/2001	Shujath M. Ali	DEX-0176	7509

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EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/787,844	ALI ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *7-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8,9,12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I, claims 1-6 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that all three restricted groups have unity. This is not found persuasive because the special technical feature in claim 1 does not contribute over art as evidenced by the art rejection below.

The requirement is still deemed proper and is therefore made FINAL.

Claims 7-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

Claims 1-11 are pending and claims 1-6 are examined on merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5 recite "CSG" but it is not clear what the metes and bounds are. The specification at page 4, the last paragraph says that CSG is a cancer specific gene and GSC refers to many things including SEQ ID NO:1.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for ovarian cancer diagnosis, does not reasonably provide enablement for any other cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification at Table 2 and pages 25-26 teaches that overexpression of SEQ ID NO:1 in ovarian cancer compared to normal control is detected. The specification does not teach whether overexpression of the marker is detected in testicular cancer or any other gynecological cancer such as breast cancer. The specification does not teach whether overexpression of SEQ ID NO:1 is also indicative that a cancer has metastasized or progressed into a next stage.

One cannot extrapolate the teachings of the specification to the claimed invention because the specification provides neither guidance on nor exemplification of how to correlate the data presented in the specification with the ability to use overexpression of SEQ ID NO:1 for the assessment of any other cancer except ovarian cancer or assessing whether cancer metastasized or progressed into different stages. Novak et al (1975, Novak's Textbook of Gynecology, Waverly Press, Inc, page 481 only) teach ovarian cancer is classified Stage I-IV. The specification does not teach what expression levels indicate Stage II as compared to Stage III of ovarian cancer, for example.

Further, the specification does not teach whether the protein encoded by SEQ ID NO:1 is also overexpressed and/or able to be detected if overexpressed.

The art recognizes cancer diagnosis, prognosis/staging using a biomarker is unpredictable. Tockman et al (Cancer Res., 1992, 52:2711s-2718s) teach considerations necessary in bringing a cancer biomarker to successful clinical application. Although the reference is drawn to biomarkers for early lung cancer detection, the basic principles taught are clearly applicable to instant invention. Tockman et al teach that prior to the successful application of newly described markers, research must validate the markers against acknowledged disease end points, establish quantitative criteria for marker presence/absence and confirm marker predictive value in prospective population trials (see abstract). Early stage markers of tumorigenicity have clear biological plausibility as markers of preclinical cancer and if validated can be used for population screening (p. 2713s, col 1). The reference further teaches that once selected, the sensitivity and specificity of the biomarker must be validated to a known (histology/cytology-confirmed) cancer outcome. The essential element of the validation of an early detection marker is the ability to test the marker on clinical material obtained from subjects monitored in advance of clinical cancer and link those marker results with subsequent histological confirmation of disease. This irrefutable link between antecedent marker and subsequent acknowledged disease is the essence of a valid intermediate end point marker (p. 2714, see Biomarker Validation against Acknowledged Disease End Points). Clearly, prior to the successful application of newly described markers, markers must be validated

against acknowledged disease end points and the marker predictive value must be confirmed in prospective population trials (p. 2716s, col 2). Lejeune et al (cited below) teach a biomarker overexpressed in benign tumor and primary breast cancer as compared to normal control does not necessarily stays overexpressed when cancer metastasized unlike overexpression-taught HER-2/new expression status, which becomes more amplified as breast cancer progresses; these teachings indicate which way the expression of a biomarker would go i.e., up and down as a gynecological cancer progresses is unpredictable. Compare the data in the instant specification to those presented in Tables I-IV of Slamon et al, which teach how much of HER-2/neu is expressed at various stages of breast cancer.

The specification provides insufficient guidance regarding the various issues discussed above, and provides no working examples of correlating staging or progression of a gynecological cancer/testicular cancer to the biomarker and/or diagnosis of any other cancer except ovarian cancer, which would provide guidance to one skilled in the art to use the claimed invention without undue experimentation. Considering lack of examples and the limited teachings of the specification, and unpredictability in the art, it is concluded that undue experimentation would be required to practice the full scope of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Lejeune et al (1995, Clin Cancer Res. Vol. 1 pages 215-22).

This rejection is based on the Office interpretation of the claim as drawn to method of gynecological cancer diagnosis by detecting overexpression of any CSG (cancer specific antigen). Lejeune et al teach at Table 2 that Wnt5a is overexpressed in breast cancer compared to normal control, thus the instant claim 1 reads on the prior art.

Claims 2-5 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. 4,968,603 (11/03/1990).

This rejection is based on the Office interpretation of the claim as drawn to method of detecting level of any CSG (cancer specific antigen) and concluding that higher level as compared to normal control indicates bad outcome as stated in the instant conclusion step of the claim i.e., cancer metastasized, progressing in stage, etc. The claims as written read on teaching of US Pat. 4,968,603 because the patent teaches HER-2/neu expression status provides prognostic indicator. Note especially Table I-IV, and claims 1-22.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
October 16, 2003

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
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